UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,558	05/08/2008	Can V Bui	30915-701.831	2816

21971 7590 06/28/2010

WILSON, SONSINI, GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	**PAPER NUMBER**
1655	

MAIL DATE	DELIVERY MODE
06/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,558	BUI ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-10,12-15,17-20,23-26,29 and 32-36* is/are pending in the application.

4a) Of the above claim(s) *18-20,23-26,29,33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-10,12-15,17,32,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 November 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed April 23, 2010 has been received and entered.

2. Claims 1, 7-10, 12-15, 17-20, 23-26, 29, 32-36 are currently pending.

Election/Restrictions

3. Applicant's election without traverse of Group I, claims 1, 7-10, 12-15, 17, 32, 35 and 36, in the reply filed on April 23, 2010 is acknowledged.

4. Claims 18-20, 23-26,29, 33 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

5. Claims 1, 7-10, 12-15, 17, 32, 35 and 36 are examined on the merits.

Claim Objections

6. Claim 8 is objected to because of the following informalities: "claims" in line 1 should be "claim". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. Claim 13 recites the limitation "The pharmaceutical composition." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001-299305 (translation provided), Katikova (Eksperimental'naia i klinicheskaia farmakologiia, (2002 Jan-Feb) Vol. 65, No. 1, pp. 41-3), CN 1127124, JP 2000-083654 (translation provided), and Lomnitski (Toxicologic Pathology (2000), vol. 28, no. 4, pp. 380-7).

JP '305 teaches using cabbage (Brassica oleracea) to protect against liver damage. The reference teaches that the composition can be in the form of a dietary supplement, juice, tablet, powder or liquid (see paragraphs 3, 4, 12 and 20 of the translation).

Katikova teaches using beet (Beta vulgaris) and carrot (Daucus carota) juice to protect against liver damage (see English abstract).

CN '124 teaches using celery (Apium graveolens) juice and honey to protect against liver damage (see English abstract).

JP '654 teaches using parsley (Petroselinum crispum) to protect the liver. The composition is in the form of an emulsion, powder, tablet, or suspension (see paragraphs 2, 8, 15 and 24 of the translation).

Lomnitski teaches using spinach (Spinacea oleracea) to protect the liver (see abstract and Discussion section).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that provide protection to the liver. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

Based on the disclosure by these references that these substances are used in compositions to provide protection to the liver, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to provide protection to the liver. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP section 2144.06, In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105

USPQ 233, 235 (CCPA 1955). The references teach that each of the claimed ingredients is a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition. Therefore, an artisan would have been motivated to modify the amount of each ingredient in the combination in order to formulate a product that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The references do not discuss the amount of potassium and calcium provided by the ingredients. However, according to Table 1 in applicant's specification, potassium and calcium are intrinsic components of the claimed ingredients. Providing the ingredients in the amounts claimed by applicant would provide the amounts of potassium and calcium claimed, as evidenced by Table 1. Thus, a composition with the claimed amounts of potassium and calcium is considered to be intrinsic in the composition taught by the combination of the references.

9. Claims 1, 7-10, 12-15, 17 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001-299305 (translation provided), Katikova (Eksperimental'naia i klinicheskaia farmakologiia, (2002 Jan-Feb) Vol. 65, No. 1, pp. 41-3), CN 1127124, JP 2000-083654 (translation provided), and Lomnitski (Toxicologic Pathology (2000), vol. 28, no. 4, pp. 380-7) as applied to claims 35 and 36 above, and further in view of WO 01/97823.

The teachings of JP '305, Katikova, CN '124, JP '654 and Lomnitski are discussed above. The references do not teach adding aloe to the composition. WO '823 teaches using aloe to treat

hepatitis (see claims 1 and 3 and paragraphs 8 and 13). This would lead to protection of the liver against damage.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that provide protection to the liver. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

Based on the disclosure by these references that these substances are used in compositions to provide protection to the liver, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to provide protection to the liver. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP section 2144.06, In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105

USPQ 233, 235 (CCPA 1955). The references teach that each of the claimed ingredients is a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition. Therefore, an artisan would have been motivated to modify the amount of each ingredient in the combination in order to formulate a product that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655